EME

Self-Monitoring Blood Glucose System

User's Manual

Please read this User's Manual thoroughly
Before using your blood glucose meter

Dear EME SMBG System Owner,

Thank you for using the **EME** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the **EME** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **EME** SMBG.

Intended Use

The **EME Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, or forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.

Important Safety Instructions

Lancets and meters are for single use only. A new, sterile lancet should be used each time you perform a test. The lancing device, lancets and meter are NOT to be shared between users or other family members. Do NOT use on multiple individuals. Sharing a lancing device and lancets may transmit blood borne pathogens, such as viral hepatitis.
All parts of the kit are considered biohazardous and may transmit infection, even if you have performed cleaning and disinfection. Wash hands thoroughly with soap and water before and after handling the meter or lancing device.

For further information, please see: *"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication"* (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Standard Accessories

The **EME** Blood Glucose meter and accessories are working together to measure the amount of glucose in your blood. The system includes:

- **Blood Glucose Meter**
- **10 Test Strips**
- **Carrying Case**
- **2 Alkaline Batteries**
- **10 Lancets**
- **Lancing Device**
- **AST Lancing Device Cap**
- **User's Manual**
- **Quick Reference Guide**
- **Log Book**
- **Level 2 Control Solution**
- **Control Solution Instructions**
- **Test Strip Instructions**

Optional Accessories

- **Level 3 Control Solution**

Note:

1. **EME Level 2 Control Solution is included with the system.**
2. **EME Level 3 Control Solution is available. For purchase, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM).**

Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We have made this SMBG system as simple as possible to help you use it regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

Do you need help?

If you have questions or need assistance, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.

Please complete your warranty card and mail it, so you receive the best customer service possible and news about product update.

Note:
Although the EME SMBG System is easy to use, you may need to consult with your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

Important Information about Your New Meter

- EME blood glucose meter is designed and approved for testing fresh capillary whole blood samples from your fingertip palm, and forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose or screen for diabetes.
- EME blood glucose meter can only be used with EME Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimens.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect readings. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car, bathroom, or refrigerator.
- Keep the meter, test strips and lancing device away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.
- Remove batteries if the meter will not be used for one month or more.

Note:

- Consult with your healthcare professional before testing on your palm and forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Up to the altitude of 10,000 feet has effect on readings.

Health-Related Information

- If you are experiencing dehydration, frequent urination, low blood pressure, shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, contact your Healthcare Professional or physician immediately. If you have questions regarding the use of the meter, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.
- Please read your test strip instructions carefully for additional health-related information.

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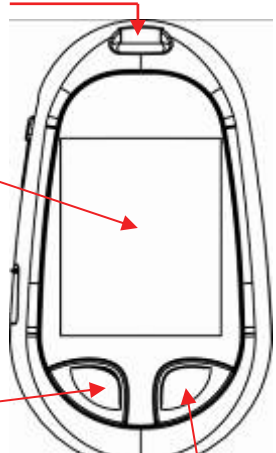
Chapter 1: Understanding Your Meter

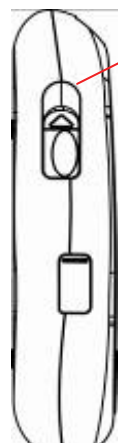
The EME Blood Glucose Meter

Test Strip Slot- Insert test strip here.

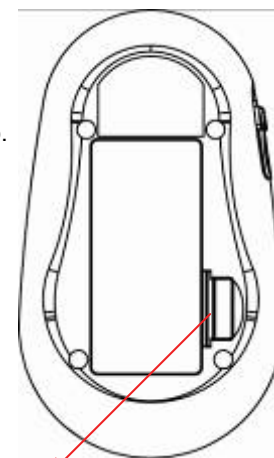
Display- Shows results, messages, and results stored in memory.

Left* (←) *Buttons- Press to enter memory, adjust setting, and scroll through results.





Strip Enjector- Push the Strip Ejector to remove the strip.



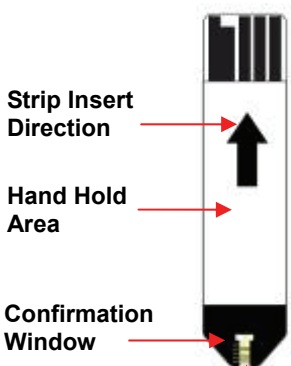
Right* (→) *Buttons- Press to turn the meter on, confirm setting, and scroll through results.

Battery Door- Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

Folder Symbol		Meaning
88-88	Date	Show the moment of month and day.
88:88	Time	Show the moment of time.
888	Test result	Show the test result.
888	Record/Average display	Tracking all the test results or average of /14/30/90 days.
CS	Control Solution	Control Solution test and the result is not included in the memory.
A	AM	Indicate before noon
P	PM	Indicate after noon
	Batteries status	When the battery symbol appears, prepare new batteries for installation.
	AC = ante cibos	Indicate before meal
	PC = post cibos	Indicate after meal
	Insert strip	Insert the test strip to test blood glucose.
	Thermometer	When the thermometer icon appears, the temperature is too high or too low.
	Error	The meter system is in fault.
M	Memory	Show the memorized results
	Apply blood	Apply blood to the test strip
mg/dL	Glucose unit	The testing unit of blood glucose is mg/dL.

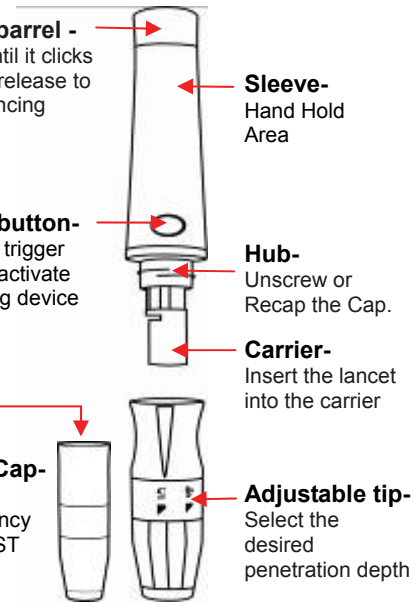
The EME Accessories

Test Strip

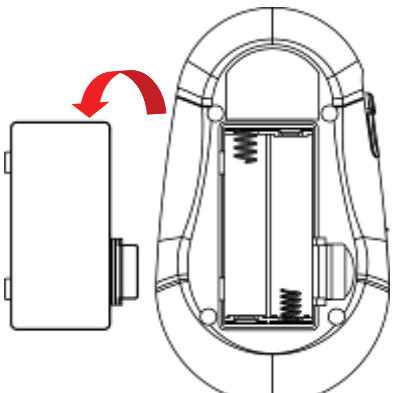


Test Strip Bottle

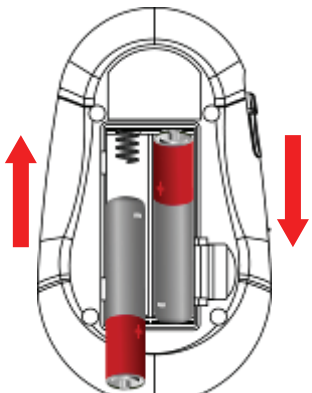
Lancing Devicing


Sliding barrel - Pull on until it clicks and then release to enable lancing device.
Sleeve- Hand Hold Area
Trigger button- Press the trigger button to activate the lancing device
Hub- Unscrew or Recap the Cap.
Carrier- Insert the lancet into the carrier
AST Lancing Device Cap- Use this transparency cap for AST testing
Adjustable tip- Select the desired penetration depth

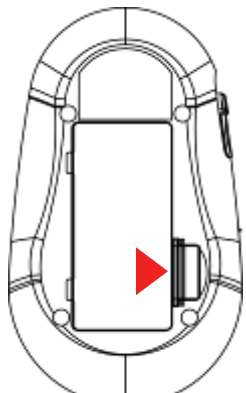
Installing Batteries



1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.



2. Insert two batteries and the meter beeps.



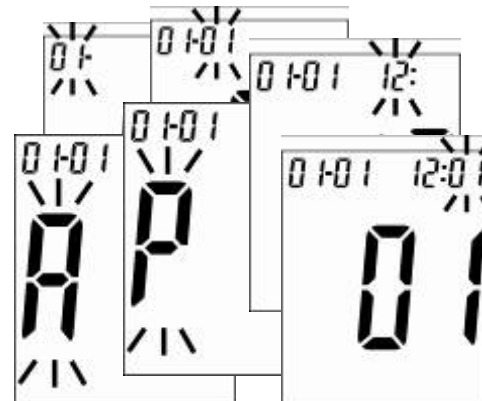
3. Put the battery door back in place and snap it closed. The meter turns on automatically.

Setting The Time and Date - First Time Use

Setting the current time and date in your meter is important if you use the meter memory.

1. Press ➔ (right button) to turn the meter on.

2. The display shows the last 2-digit of the year that flashes at the top of display as well. Press ← (left button) to adjust the year and press ➔ (right button) to confirm the setting.



3. Repeat step 2 to set the date and time. The flashing field is the one you are currently setting. (A=AM, P=PM)

Using EME Blood Glucose Test Strips

- Use only with EME Blood Glucose Meters.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, tightly close the bottle immediately. This keeps the test strips dry.
- Use the test strip within three minutes after taking it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the expiration date on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 35.6°F - 86°F (2°C ~30°C). Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.
- EME Self-Monitoring Blood Glucose Test System is a “no code” system and does not require any test strip calibration.

Chapter 2: Control Solution Testing

Why Run a Control Solution Test

We recommend that you run the EME level 2 and level 3 control test because it lets you know that your meter and test strips are working properly to give reliable results. You should run the control solution tests when:

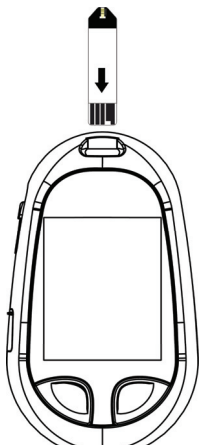
- You use the EME Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.

About The Control Solutions

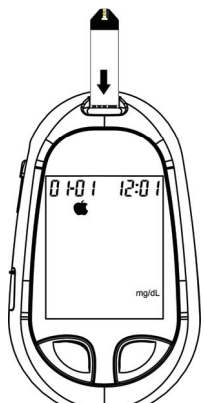
- Use with EME test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solutions can stain clothing. If you spill the solution, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store control solution at room temperature, between 35.6°F - 86°F (2°C~30°C). Do not freeze.
- If you would like to purchase EME level 2 and level 3 Control Solutions, please contact your local dealer.

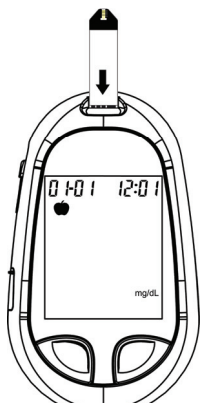
Running a Control Solution Test

You need the meter, a test strip, and control solution.



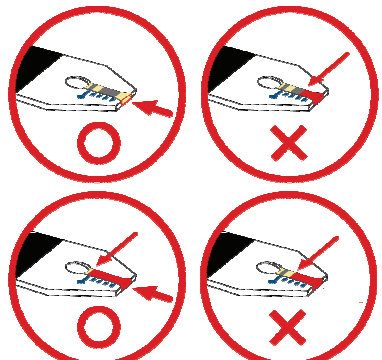
1. Put a test trip into the meter as the direction of the arrow on the test strip. The meter turns on automatically.





2. Press ← (left button) to set (AC), (PC) or CS Mode, then press → (right button) to confirm the setting.

3. The icons and show themselves.



4. Place the meter on a flat surface, like a table.

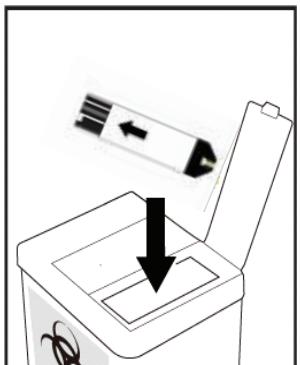
5. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

6. Squeeze the bottle until a tiny drop forms at the tip of the bottle.

7. Touch the drop at the tip of the test strip.

8. The meter starts to count down from 5 seconds and then shows the test result.

9. Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.



10. Push the Strip Ejector to Remove the test strip.

11. Throw the test strip away after you have compared the reading to the range printed on the test strip bottle.

Understanding Control Solution Test Results

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside this range. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:

Note:

1. If "C5 " is not set, then the control test values will be counted into 7/14/30/60/90 days average mode.

2. If "C5 " is set, the control solution values will not be counted into averages, but only in the memory for review.

Troubleshooting Checks	***Action***
✓ Was the test strip exposed to open air for a long period of time?	Repeat the control test with properly stored strips.
✓ Does the cap on the bottle keep tightly prevent moisture or humidity from affecting strips?	If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.
✓ Is the control solution expired or contaminated?	Replace with new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	Repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	If you have followed the steps properly, contact physician. If you continue to have problems please contact Customer Support at 1-866-994-3345.

Chapter 3: Testing Your Blood Glucose

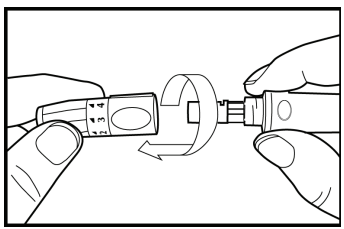
Using the Lancing Device

- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.
- If the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. For the disinfection instruction, please refer to Chapter 5: Maintenance And Troubleshooting "Cleaning and disinfect your meter".

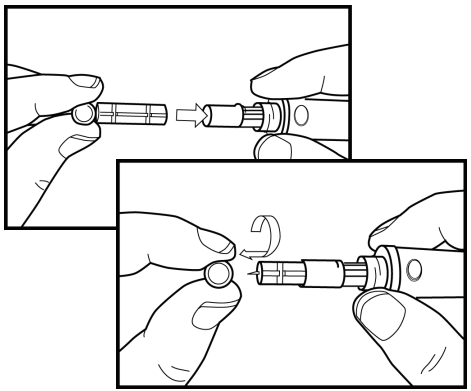
Note:
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing used test strips and lancets with their doctor.

Inserting a Lancet into the Lancing Device

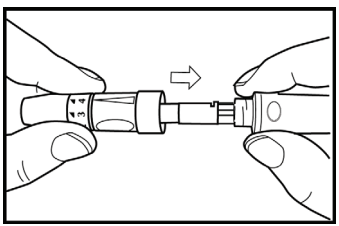
You must first load the lancet into the lancing device to get it ready for use.



1. Unscrew the Cap.

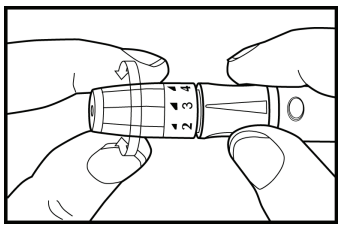


2. Insert the lancet into the lancing device firmly then twist off the protective cover.

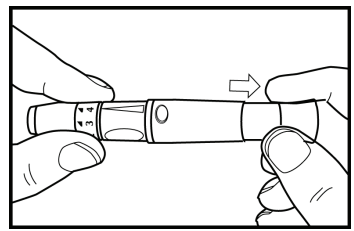


3. Recap the front cap.

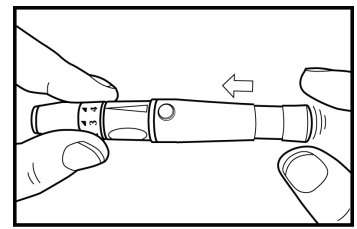
Note:
Lancets are for single use only and a new, sterile lancet should be used each time you perform a test.



4. Select the desired penetration depth.



5. Pull on the sliding barrel of the lancing device until it clicks and then release.
Now the lancing device is ready.
Do not prick your finger until your meter and strip are prepared.

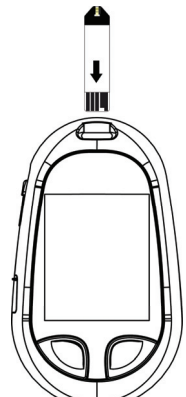


6. Set the lancing device aside until later in the test.

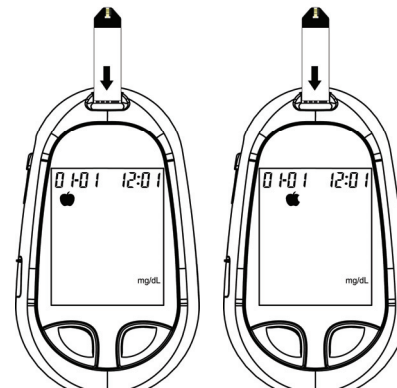
Note: 1. Select 1-2 for soft or thin skin, 3 for average, and 4-5 for thick or calloused skin.
2. Lancing device and lancets are not to be shared between users. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.

Running a Blood Glucose Test with Blood from Your Fingertip

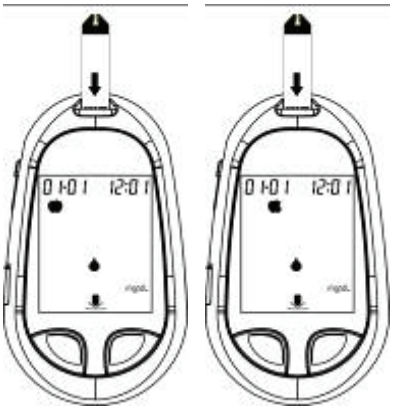
1. Wash your hands with soap and warm water.
Rinse and dry thoroughly.



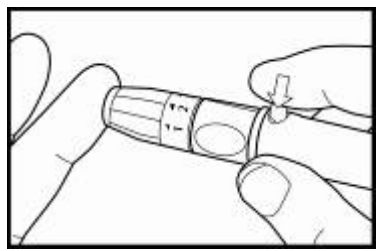
2. Put a test strip into the meter in the direction of the arrow. The meter turns on automatically.



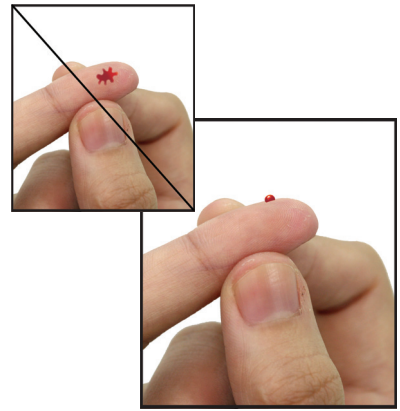
3. Press ← (left button) to set (AC) or (PC) Mode, then press → (right button) to confirm the setting.



4. The icons and show themselves.
When the blood drop flashes on the display, obtain a drop of blood from your finger.



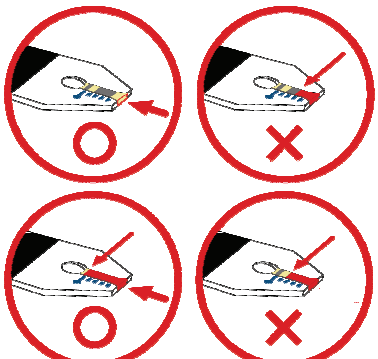
5. Hold the lancing device firmly against the side of your finger. Press the trigger button. Then remove the lancing device from your finger.



6. Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.

7. Wipe away the first drop with a tissue and use the second drop.

Note: please make sure to apply blood when the blood drop appears on the display.



8. Touch the drop to the tip of the transparent window of the test strip.
Do not put blood on top of the strip.
Be sure to get enough blood in the strip's confirmation window. Otherwise, an inaccurate reading may yield.

9. The meter starts to count down from 5 seconds and then shows the test result.

10. Push the Strip Ejector to remove the test strip.
11. Throw it away after you have compared the reading to the range printed on the test strip bottle.

Alternative Site Testing (AST)

Understanding Alternative Site Testing

What is AST?
Besides the fingertip, you can test your palm or forearm.

What is the advantage of AST?
You have the option of testing other places on your body besides the fingertip.

Consult your health care professional before you begin using the palm or forearm for testing. Blood glucose test results obtained from your palm or forearm may differ significantly from fingertip samples.

We strongly recommend that you:

Do AST ONLY in the following intervals:
- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do NOT use AST if:
- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- If you are pregnant.

Fingertip test only:

- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- After injecting rapid-acting insulin (two hours or less)

What NOT to do:

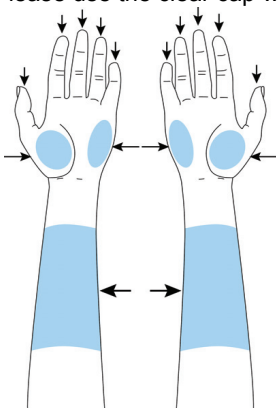
- If the blood glucose test result from the alternative site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of *an alternative site* result, do a fingertip test to confirm the result.
- If you often do not notice when your blood glucose is low, do a fingertip test.

Caution:

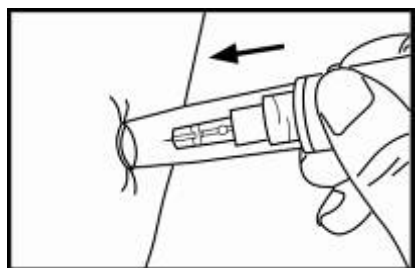
- Talk with your healthcare professional before you test palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm samples.
- Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.

Running a Blood Glucose Test with Blood from Your Palm or Forearm

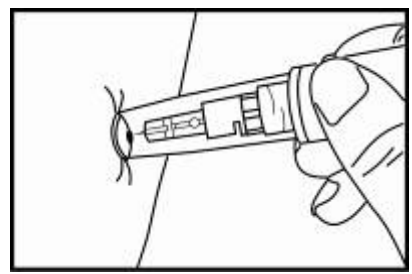
Please use the clear cap with the lancing device for AST testing



1. Massage the puncture area of forearm for a few seconds.



2. Press and hold the device with clear adjustable tip against the forearm.

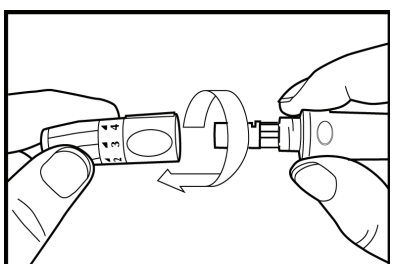


3. Press the trigger button to activate the lancing device. Hold the device against forearm and increase pressure until the blood sample size is sufficient.

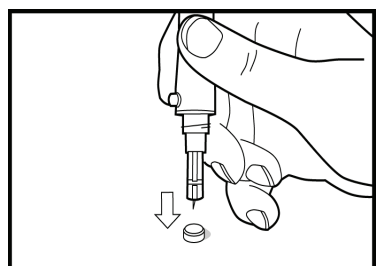
4. Wipe away the first drop with a tissue and use the second drop.

■**Note:** **1. Check with your healthcare professional before testing sites other that the fingertip.**
2. Please do NOT use the first drop of blood sample.

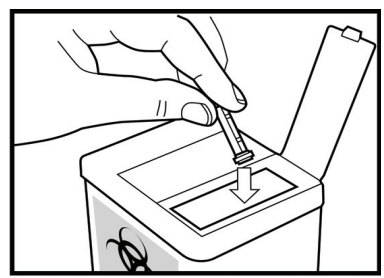
Discarding Used Lancets



1. Unscrew and remove the adjustable cap.



2. Pull on the sliding barrel of the lancing device and slide the ejection control at the same time. The used lancet will be pushed out.



3. Discard used disposable lancets into an appropriate sharps or biohazard container.

Expected Values*

The EME Blood Glucose test strips are whole-blood referenced and calibrated for easier comparison to lab results. The American Diabetes Association recommends the following values to normal people without diabetes*:

A post-meal glucose level of less than 180 mg/dL
A pre-meal glucose of 70–130 mg/dL

For people with diabetes: please consult with your doctor for the appropriate blood glucose range.

Unusual Test Results

If your test result does not match the way you feel, please follow these steps:

1. Run a control test, Chapter 2, "Control Solution Testing."
2. Repeat a blood glucose test, Chapter 3, "Testing Your Blood glucose."
3. If your test results still do not reflect the way you feel, call your doctor immediately.

Note:

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.**
2. **Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results.**

Comparing Your Meter Result to a Lab Result

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than your **EME** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

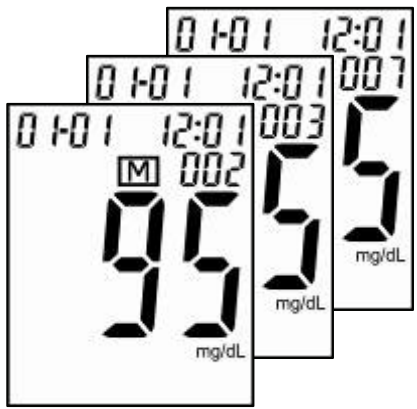
Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.

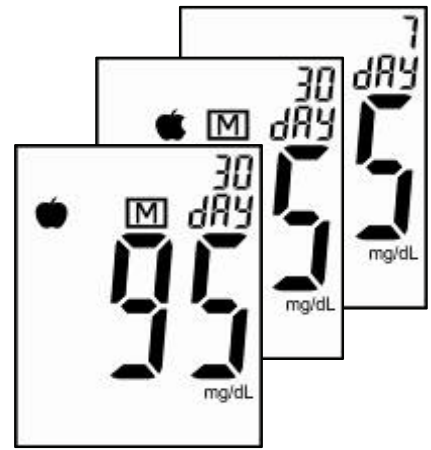
Note:

1. **Do not change your therapy based on one individual result in memory.**
2. **The memory is not lost when you replace the battery. You do need to check that the time and date are still correct for future readings. See Section "Setting the time and date" in Chapter 1.**
3. **Once 480 results are in memory, adding a new result causes the oldest one to be deleted.**

Viewing Test Results

The meter provides 7, 14, 30 and 90 days averaging to help track your blood glucose result soundlessly.



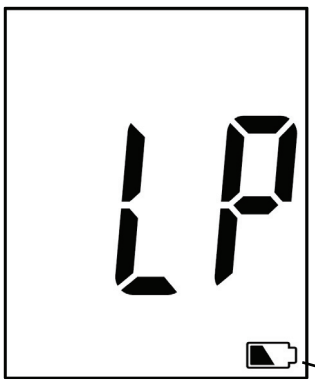


1. Press ➔ until turning the meter on.
2. Press ← to view the latest test result.
3. All results are shown in turn from records of M480 to M001.

4. Press ➔to view averages of 30day-AC/PC and 7/14/30/90 days.

Chapter 5: Maintenance and Troubleshooting

Installing Batteries



The meter uses two alkaline 1.5V (AAA) batteries. Batteries will normally last for more than 2000 tests. Other types of 1.5V (AAA) batteries are also acceptable, but the capacity of test times may differ. Install the batteries when you first use the meter or replace with new batteries when the "LP" (low power) message and the low battery symbol appear on the display.

The meter will not turn on the first time batteries are installed. Please press and hold "➔" button or insert the test strip to turn your meter on.

The meter will turn off automatically. Or you can press and hold "➔" button to turn your meter off.

Low battery symbol

Note:

1. **The meter won't delete earlier records after you replace batteries.**
2. **You should reset the time and date again after you replace the batteries.**
3. **1.5V (AAA) x 2 batteries are available at most stores. You may take the old batteries with you for replacement.**
4. **Remove batteries when you will not be using the meter for one month or more.**

Cleaning and Disinfecting Your Meter and Lancing Device

Choosing the disinfectant

The recommended EPA-registered disinfected product is as follow:

PDI® Super SANI-CLOTH® Germicidal disposable wipe (EPA Reg. No.:9480-4)

Super Sani-Cloth germicidal wipe contains active ingredients: n-Alkyl (60% C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chlorides and n-Alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chlorides and they have been shown to be safe for use with the EME meter, but any other disinfectant product with the EPA registration number may be used on this device.

Please find the Super Sani-Cloth germicidal wipe in any pharmaceutical store or purchase on the PDI website: http://www.pdipdi.com/healthcare/surface_disinfect.aspx

Cleaning and Disinfection Instruction

Please keep the meter and lancing device free of dirt, dust, bloodstain, and water stains. EME blood glucose meter and lancing device should be used only on one patient and not shared. Follow these guidelines carefully to clean your meter

After every use (for up to 9 times a day), follow the cleaning instruction to prevent the growth of any microorganism and also to help improving the effectiveness of disinfection. Then follow disinfection instruction once per week which could effectively kill blood borne pathogens, such as viral hepatitis and prevent cross-contamination. Therefore, if the meter and lancing device are being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Cleaning Instruction: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold and use first germicidal wipe to remove heavy soil after every use.

Disinfection Instruction: Unfold a clean wipe and thoroughly wet all the surface of the meter, including the strip port and other connection port. Unfold a clean wipe and thoroughly wet all the surface of the lancing device, including cap or AST cap if used. Treated area must remain visibly wet for a full 2 minutes. Let the devices air dry for 0.5 minute. Do disinfection once per week.

Do:

- Make sure the meter is turned off during cleaning and disinfection.
- Keep the test strip vials tightly closed when performing the cleaning and disinfection procedures because the fumes from the disinfectant may affect the performance of the strip
- After cleaning or disinfection, please perform the physical appearance and performance check of devices. Please follow the instruction on the page 41 to 43.

Do Not:

- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

Physical Appearance check of the meter after each cleaning or disinfection

Check item	Accept Result
Is it clear to see through the transparency part, like display?	Yes
Is the strip slot and other components free from erosion?	Yes
Is the labeling on the meter legible?	Yes
Action: If any of the results is “No” the user should call the Customer Care Service toll-free at 866-994-3345(Eastern Time, Mon-Fri 9:00AM~5:00PM) for assistance.	

Performance check of the meter

Steps	Check item	Accept Result
After each cleaning		
1. Press and hold left button for 3 sec.	Is the meter powered on?	Yes
	Did the meter beep?	Yes
2. Press and release right button.	Is the testing result correctly stored in the memory?	Yes
	Can the result be clearly read?	Yes

After each disinfection		
1. Insert test strip	Is the meter powered on?	Yes
2. Apply Level 2 control solution	Any reading?	Yes
	Is the reading within control range?	Yes
3. Remove test strip	Is the meter powered off?	Yes
4. Press and hold left button for 3 sec.	Is the meter powered on?	Yes
	Did the meter beep?	Yes
5. Press and release right button.	Is the testing result correctly stored in the memory?	Yes
	Can the result be clearly read?	Yes
Action: If any of the results is “No”, stop using the device. Please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM) for replacement with a new meter.		

Physical Appearance check of the lancing device after each cleaning or disinfection

Check item	Accept Result
Are all components free from erosion?	Yes
Action: If any of the results is “No” the user should call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM) for assistance.	

Performance check of the Lancing device

Step	Check item	Accept Result
After each cleaning		
1.Cap the normal cap to the lancing device.	Can the cap be screwed on the lancing device?	Yes
2. Pull on the sliding barrel and then release.	Can the lancing device click?	Yes
3. Press trigger button.	Can the lancet be fired?	Yes
After each disinfection		
1. Install the lancet on the lancet holder.	Can the lancet be fixed on the lancet holder?	Yes
2. Cap the AST cap to the lancing device.	Can the AST cap be screwed on the lancing device?	Yes
3. Remove the AST cap. Recap the normal cap to the lancing device.	Can the cap be screwed on the lancing device?	Yes
	Can the penetration depth ring be adjusted?	Yes
4. Pull on the sliding barrel and then release.	Can the lancing device click?	Yes
5. Press trigger button.	Can the lancet be fired?	Yes
Action: If any of the results is "No", please call the Customer Care Service toll-free at 866-994-3345(Eastern Time, Mon-Fri 9:00AM~5:00PM) for replacement with a new device.		

Cleaning and Disinfection Frequency

At least **9** cycles of cleaning per day and **1** cycle of disinfection per week with allow the user to use the device for **4** years. The meter can sustain at least 20,000 cycles of cleaning and disinfection and the lancing device can sustain at least 14,600 cycles of cleaning and disinfection.

Cleaning Frequency: 9 cycles/day X 365 days/year X **4** year product life = 13,140 cycles of cleaning

Disinfection Frequency: 1 cycle/week X 52 weeks/year X **4** year product life = 208 cycles of disinfections

< 20,000 validated cycles of cleaning and disinfection for the meter

<14,600 validated cycles of cleaning and disinfection for the lancing device

4 year product life is for properly cleaning and disinfection. After 4 years, the meter must be replaced with a new meter.

Maintenance and Testing

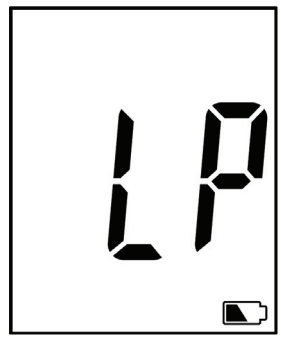
Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

To make sure the display is working properly, turn off the meter. Press and hold "➜" to see the complete display. All the indicators should be clear and look exactly like the picture to the left. If not, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

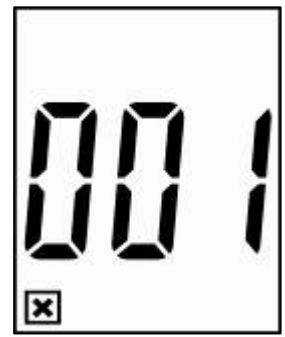
Screen Messages and Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM).

Humidified/Used strips
Action: Replace with a new strip.



Low power
Action: Replace with new batteries.



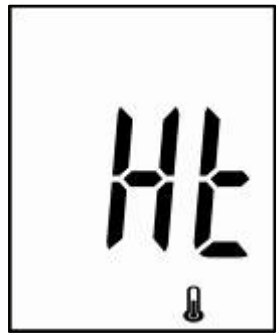
System fault
Action: Replace the batteries first. If **ERROR 001** appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

System fault
Action: Replace the batteries first. If Err appears again, please call the Customer Care Service toll-free at 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your local dealer.

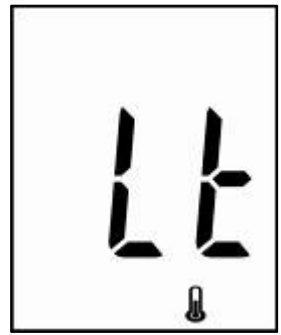
Test result is higher than 600 mg/dL.
Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please call your health care provider.

The test result is lower than 20 mg/dL.
Action: Test again. If the result is still the same, try a control solution test and if the control solution test falls within the correct range, please call your health care provider.

Err message. Not enough sample was drawn into the test strip for measurement.
Action: Discard the test strip and repeat the test..



The ”Ht” and thermometer icon appears. Temperature is too high, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.
Action: Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).



The ”Lt” and thermometer icon appears. Temperature is too low, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.
Action: Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).

Chapter 6: Technical Information

Specifications

Brand name		EME Blood Glucose Meter
Range		20~600 mg/dL
Response time		5 seconds
Memory sets		480 test results
Operating condition	Temp.	50°F -104°F (10°C-40°C)
	Relative Humidity	R.H. ≦ 90%
Storage and transportation condition	Temp.	35.6°F -86°F (2°C -30°C)
	Relative Humidity	40-85 % RH
Blood sample		0.6 μL
		Fresh capillary blood from fingertip, palm, or forearm
Hematocrit (Hct)		20~60%
Power		2 Alkaline 1.5V (AAA)
Battery life		Over 2000 tests
Display dimension		35.0 × 43.0 mm
Device dimension H × W × D (mm)		98 x 57 x 22 mm
Weight		43.2 grams w/o battery
Principles		Electrochemical biosensor technology

Limitations

The test strips are used for fresh capillary whole blood samples.

1. DO NOT use neonate blood sample.
2. Not to be used for diagnosis or screening of diabetes.
3. Alternative site testing with this system can be used only during steady-state blood glucose conditions.
4. Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.
5. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
6. The system should be used at a temperatures between 50°F and 104°F(10°C and 40°C). Outside this range, the system may get incorrect results.
7. DO NOT reuse the test strips. The test strips are for single use only.
8. Hematocrit: The hematocrits between 20% and 60% will not significantly affect the results. Hematocrit below 20% may cause higher results. Hematocrit above 60% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
9. Altitude up to10,000 feet above sea level has no effect on readings.
10. The below substances up to the test concentration will not affect the test results.

Interfering substance	Concentration tested up to (mg/dL)
Gentisic Acid	6
Ascorbic Acid	4
Ibuprophen	50
Methyldopa	2
Sodium Salicylate	50
Tetracycline	1.5
Tolbutamide	100

Galactose	20
Maltose	20
Manose	10
Sucrose	50
Xylitol	200
Glipizide	8
Bilirubin	25
Cholesterol	500
Creatinine	30
Triglycerides	1000
Fructose	30

11. Interference was observed with the substances below at the concentrations listed.

Interfering substance	**Interference observed at (mg/dL)**
Acetaminophen	8
Dopamine	5.2
L-Dopa	4
Xylose	8
Uric Acid	15.9

Device Information

EME SMBG System,
EME Blood Glucose Test Strips,
EME Blood Glucose Meter,
EME Level 2 Control Solution,
EME Level 3 Control Solution

Reference:

* American Diabetes Association. Standards of medical care in diabetes-Table 10 Diabetes care. 2011; Vol. 34, Suppl. 1, S21.

Manufacturer:

EPS BIO TECHNOLOGY CORP.
No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077
TEL：+886-3-6686868 FAX：+886-3-6686866
E-mail：info@epsbio.com.tw Website：http://www.epsbio.com.tw

Lancing Device

Meets the requirements of MDD 93/42/EEC

Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

No. 32 Xinlian RD. Pingjiang Suzhou P.R. China 215031
TEL：0086 (512) 67217661 FAX：0086 (512) 67217663
E-mail：guopings@xinda-medical.com

Lancet

Meets the requirements of MDD 93/42/EEC

Manufacturer:

SAE HAN MEDICAL CORP.

700-113 PUB GOT-DONG, IL SAN-GU, GOYANG-CITY, KYUNGGI-DO, KOREA
TEL：82-31-923-4330 FAX：82-31-923-4331
E-mail：saehan@saehanmed.com

Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if the Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

Please read EME User's Manual before operation. If you have any questions and/or need assistance, please contact us as follows:
Within the USA, call toll-free: 866-994-3345 (Eastern Time, Mon-Fri 9:00AM~5:00PM). During non-service hours, please contact your healthcare provider.
Outside the USA, call your authorized representative or write to:
Customer Service E-mail: info@epsbio.com.tw

Distributor:

GEMCO MEDICAL

5640 Hudson Industrial Parkway P.O. Box 429, Hudson, OH 44236
Customer Line： 800-733-7976 Fax：330-342-9444
Website：http:// www.gemcomedical.com

P/N: 71800270A Rev.X01